DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive SE
Bothell, WA 98021-4421

Telephone: 425-486-8788
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August 11, 2000

VIA FEDERAL EXPRESS

RE: Inspection ID - 1392040007

Gary Peck, Chief Executive Officer
St. Joseph's Hospital of Chewelah
500 East Webster
Chewelah, Washington 99109

WARNING LETTER

Dear Mr. Peck:

We are writing to you because on August 1, 2000, your facility was inspected by a representative of the State of Washington, Kelly Cameron, acting in behalf of the Food and Drug Administration (FDA). This inspection revealed a serious regulatory problem involving the mammography at your facility.

Under a United States Federal law, the Mammography Quality Standards Act of 1992, your facility must meet specific requirements for mammography. These requirements help protect the health of women by assuring that a facility can perform quality mammography. The inspection revealed the following Level 1, Level 2 and repeat Level 3 findings at your facility:

- Level 1: Processor QC records were missing 4 out of 13 days of operation in the month of February, 2000. Processor QC records missing 31%, for processor 0000000001, [redacted], room Darkroom at site St. Joseph's Hospital of Chewelah.

- Level 2: The time period between the previous and current surveys for x-ray unit 2, [redacted] exceeds 14 months.

- Level 2: Processor QC records were missing 3 consecutive days for processor 0000000001, [redacted], room Darkroom at site St. Joseph's Hospital of Chewelah.

The specific problems noted above appeared on your MQSA Facility Inspection Report, which was issued to your facility at the close of the inspection.

Because these conditions may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, they represent a serious violation of the law which may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to: placing your facility under a Directed Plan of Correction, charging your facility for the cost of on-site monitoring, assessing civil money penalties up to

$10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, the Standards, suspension or revocation of your facility's FDA certificate, or obtaining a court injunction against further mammography.

It is necessary for you to act on this matter immediately. Please explain to this office in writing within fifteen (15) working days from the date you received this letter:

- the specific steps you have taken to correct all of the violations noted in this letter;
- each step your facility is taking to prevent the recurrence of similar violations;
- equipment settings (including technique factors), raw test data, and calculated final results, where appropriate; and
- sample records that demonstrate proper record keeping procedures, if the findings relate to quality control or other records (Note: Patient names or identification should be deleted from any copies submitted).*

Please submit your response to Thomas S. Piekarski, Compliance Officer, at the above address.

Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter pertains only to findings of your inspection and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, Food and Drug Administration, P.O. Box 6057, Columbia, Maryland 21045-6057 (1-800-838-7715) or through the Internet at http://www.fda.gov.

Sincerely,

Charles M. Breen
District Director

copy: Priscilla F. Butler, M.S.
Director, Breast Imaging Accreditation Programs
Standards and Accreditation Department
American College of Radiology
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*This note is not applicable for letters that also address patient notification.